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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,248	12/04/2003	Paul Dicarlo	01194-824001	7802
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FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER DRYDEN, MATTHEW DUTTON	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/728,248	<b>Applicant(s)</b> DICARLO ET AL.	
	<b>Examiner</b> Matthew D. Dryden	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 9-21 is/are rejected.
- 7) ☒ Claim(s) 3-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/4/2005, 5/6/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: the word "be" on line 7, page 4 of the specification should be deleted.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Biopsy device with rotating stylet assembly.

### ***Claim Objections***

Claims 5-8 are objected to because of the following informalities: claim 5 recites the limitation of the second part, there is no second part in claim 1, claim 5 should refer back to either claim 3 or claim 4. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Haaga (5718237).

Regarding claim 1, Haaga discloses a biopsy needle:

a housing having a proximal end and a distal end (can be seen around element 10 in Figure 1),

a stylet having a portion in the housing (around element 60 in Figure 4), the stylet being movable between a first extended position and a first retracted position (see Column 6, lines 44-46, and the stylet can be configured to rotate when moved from the first retracted position to the first extended position (for rotation of the stylet see column 7, lines 8-11),

a cannula coaxially receiving the stylet (element 12 in Figure 2), the cannula being movable between a second extended position and a second retracted position (see Column 6, lines 44-46, also see Column 7, lines 10-12).

Regarding claim 11, the edge of the notch of stylet (element 16 in Figure 4), can be viewed as sharp.

Claims 15, 17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachir (5660186).

Regarding claim 15, Bachir discloses a method of using a medical instrument comprising the steps of:

moving a stylet from a first position to a second position (see Column 6, lines 41-48),

simultaneously rotating the stylet along an axis of the stylet (see Column 6, lines 41-48),

and moving a cannula over the stylet (see Column 6, lines 49-58).

Regarding claim 17, the gutter of element 48 in Figure 3, can be viewed as a notch (see Column 6, lines 41-48).

Regarding claims 20 and 21, see column 6, lines 5-65.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga in view of Terwilliger et al (5146921). Haaga discloses the claimed invention except for the device comprising a stylet block attached to the proximal end of the stylet. Terwilliger et al teach it is known to provide a stylet block attached to the proximal end of the stylet (see Column 8, lines 25-34) so that the stylet can be advanced and retracted by the block, which provides a stabile base for the stylet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga to include a stylet block attached to the proximal end of the stylet, as taught by

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Terwilliger et al, so that the stylet can be advanced and retracted by the block, which provides a stabile base for the stylet.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga in view of Chu et al (5989196). Haaga discloses the claimed invention except for the device comprising a stylet spring capable of moving the stylet, and a cannula spring capable of moving the cannula. Chu et al teaches it is known to provide a biopsy needle with a cannula spring (element 40, Figure 3) and a stylet spring (element 44, Figure 3) for selectively moving the cannula and stylet from the retracted position to the extended position (see Columns 3-4, lines 31-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga to include a stylet spring and a cannula spring, as taught by Chu et al, for selectively moving the cannula and stylet from the retracted position to the extended position.

Regarding claim 10, Haaga discloses the claimed invention except for the device comprising a first and second pivoting latch for the stylet and the cannula. Chu et al teaches it is known to provide a biopsy needle with pivoting latches for the stylet and cannula (elements 60 and 52 in Figure 3) to retain the stylet and cannula in the retracted position until the switch has been moved (see Columns 3-4, lines 31-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga to include a first and second pivoting latch, as taught by Chu et al, to retain the stylet and cannula in the retracted position until the switch has been moved.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga in view of Kass (5921943). Haaga discloses the claimed invention except for the device comprising a notch having two openings and an opening opposing the notch. Kass teaches it is known to provide two openings for a notch, which can also be viewed as a notch and an opening opposing the notch (which can be seen in Figure 19) for receiving tissue that has been cut by cutting cannula (see Column 9, lines 15-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga with a notch having two openings and an opening opposing the notch, as taught by Kass, for receiving tissue that has been cut by cutting cannula.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga ('237) in view of Haaga (5394887). Haaga ('237) discloses the claimed invention except for the notch comprising a ramped surface. Haaga ('887) teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Haaga ('237) with a stylet having a notch with a ramped surface, as taught by Haaga ('887), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachir in view of Edwards et al (5607389). Bachir discloses the claimed method except for the step of oscillating the stylet along the access. Edwards et al teach it is known to provide a medical probe with a biopsy stylet with a method step of oscillating the stylet along the axis to facilitate the cutting action of the stylet into the tissue (see Column 10, lines 53-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Bachir to include the step of oscillating the stylet, as taught by Edwards et al, axis to facilitate the cutting action of the stylet into the tissue.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachir in view of Mallaby (5249583). Bachir discloses the claimed method except for the step of removing the sample from the notch with an object. Mallaby teaches it is known for the technician to remove the sample from the notch (see Columns 5-6, lines 62-9), but does not disclose to use an object to remove the sample however this is obvious because the user is at risk of he/she attempts to remove the sample with their hand. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Bachir with a step of removing the sample from the notch with an object, as implied by Mallaby, to reduce the risk of injury to the user while operating the stylet and cannula assembly.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachir in view of Mallaby, as applied to claim 18 above, and further in view of Haaga (5394887). Bachir as modified teaches the claimed method step except for the device having a



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ramped portion on the stylet, Bachir as modified does teach removal of the sample from the notch of the stylet. Haaga ('887) teaches it is known to provide a stylet with notch having a ramped surface (see Figure 3 around elements 38 and 40), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch (see Column 2, lines 52-55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Bachir with a stylet having a notch with a ramped surface, as taught by Haaga ('887), to secure the stylet in the tissue against withdrawal of the of the stylet while the cutting cannula is advanced forward to complete the cutting and capturing of the specimen in the notch.

***Allowable Subject Matter***

Claims 3-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,673,023 Pflueger discloses a micro-invasive breast biopsy device

U.S. Pat. No. 5,876,354 Quinn et al discloses a biopsy needle hub assembly

U.S. Pat. No. 5,511,556 DeSantis discloses a needle core biopsy instrument.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

  
MAX HINDENBURG  
COMMUNITY PATENT EXAMINER  
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